

September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.



American Cyanamid Company
Agricultural Products Research Division
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Mr. Jason Robertson
Special Review and Reregistration Division [7508W]
U.S. Environmental Protection Agency
Crystal Mall, Bldg. #2, Rm. 266A
1921 Jefferson Davis Highway
Arlington, VA 22202

November 7, 1997

RECEIVED

NOV 20 1997
OFF PUBLIC DOCKET

RE: Phorate Reregistration - Submission of Developmental/Reproductive Studies;
Case No. 103; TRANSMITTAL LETTER.

Dear Mr. Robertson:

American Cyanamid Company is hereby submitting two studies to support the reregistration of phorate. The first study is a rodent teratogenicity study (Guideline 83-3). Although EPA already has an acceptable rat developmental study (see MRID 00122775), the enclosed study reinforces that phorate is not a developmental toxicant. The maternal and developmental NOEL (0.3 mg/kg/day) in the enclosed study is the same as that found in the earlier work.

The second study is a 2-generation rat reproduction study in which the NOEL for parental, and growth and developmental toxicity was 0.19 mg/kg/day and the NOEL for fertility and mating behavior was 0.66 mg/kg/day, the highest dose tested. These data are being submitted to fulfill the requirement for an acceptable Guideline 83-4 study and show that phorate is not a reproductive toxicant.

It should be noted that American Cyanamid Company was first made aware of the lack of an acceptable reproduction study after receipt of the draft phorate reregistration science chapters on August 11, 1997. This information was conveyed by the Agency 3 1/2 years after the previously submitted and acceptable 3-generation mouse reproduction study (see MRID 00092853) was down-graded from core minimum to unacceptable by the HED/RfD Peer Review Committee on December 30, 1993. Had we known that the 3-generation mouse reproduction study was down-graded to unacceptable, the enclosed study would have been submitted much sooner.

The submission of the new reproduction study has a direct bearing on the Uncertainty Factor (UF) issued for phorate in the Agency's Health Effects Division memo of September 25, 1997 from J. Rowland to M. Metzger. In the memo, an additional 10X uncertainty factor (for a total of 1000X) was added in part due to the lack of an acceptable 2-generation reproduction study. We respectfully suggest the Agency reconsider the UF issued to phorate in light of the new reproduction effects data.

Thank you for your help with regard to the reregistration of phorate. Should you have any questions, I can be reached at telephone number 609-716-2378, facsimile number 609-716-2333, or by e-mail at wrubelj@pt.cyanamid.com.

Sincerely,

John J. Wrubel
Product Registrations Manager
U.S. Plant Regulatory Affairs

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TRANSMITTAL DOCUMENT

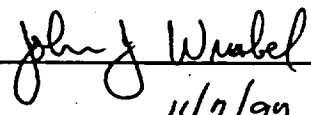
Transmittal Date: 11/7/99

Submitted By: American Cyanamid Company
Agricultural Products Research Division
P.O. Box 400
Princeton, NJ 08543-0400

In Support Of: THIMET® soil and systemic insecticide
EPA Reg. No. 241-213
Registration Case No. 103

Volume	Title	MRID No.
1	Administrative Material (cover letter)	No Data
2	Transmittal Document	No Data
3	An Oral Developmental Toxicity (Embryo-Fetal Toxicity/Teratogenicity) Definitive Study with AC 35024 in Rats; Guideline No. 83-3 (OPPTS Guideline 870.3700)	44422301
4	A Two-Generation (Two Litters) Reproduction Study with AC 35024 to Rats; Guideline No. 83-4 (OPPTS Guideline 870.3800) 7 Books [contains pages 236a and 1219a]	44422302

Company Official: John J. Wrubel

Signature: 
Date: 11/7/99

Company Name: American Cyanamid Company

Company Contact: John J. Wrubel

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File 12/12/97

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

Jane Peterson

AMERICAN CYANAMID COMPANY
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Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/12/97. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.